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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,180	HARIRI, ROBERT J.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54 and 60-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54 and 60-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/26/04 has been entered.

The response and amendment filed June 18, 2004 have been entered. Claim 54 has been amended. Claims 1-6, 9, 10, 12-18 have been canceled. Claims 61-68 are newly submitted. Claims 54, and 60-68 are pending in the application and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims and response will not be reiterated.

Priority

This application is a CIP of US patent application 10/004,942, and claims priority from U.S. provisional application 60/268, 560, and 60/251,900, filed 12/6/2000. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). In the instant case, the concept of using the placenta to culture (comprise a cell neither fetal nor maternal in origin) exogenous cells was not introduced until the filing of U.S. patent application 10/004,942, accordingly the priority date of the instantly claimed subject matter has been established as the filing date of the U.S. patent application 10/004,942, i.e. December 5, 2001. Applicants however is invited to point to the evidence to the contrary.

Claim Objections

Claim 54 is objected to because of the following informalities: the word "mammalian" should be inserted before "placenta" to make clear that plant placenta is not encompassed by the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54, and 60-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731, 737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided. The factors most relevant to this rejection are the levels of the skilled in the art, and whether sufficient amount of direction or guidance are provided in the specification to enable one of skill in the art to practice the claimed invention.

Claim 54 is drawn to a placenta, perfused to and maintained in a bloodless condition, and comprises a cell that is neither fetal nor maternal in origin. In light of the specification, the claimed placenta is the intermediate product of at least the following processes (§ 5.4 of the specification): as a bioreactor for the propagation of exogenous cells, or for producing embryonic-like stem cells by engrafting a cell not derived from the placenta into the placenta (page 26, lines 20-24).

With respect to the first process, as a bioreactor for propagating exogenous cells, the specification fails to give any detail concerning how to propagate exogenous cells in a placenta having a significant size/volume and complicated structure. It is a common

knowledge that the mammalian placenta comprises at least two highly vascularized membranous envelopes, amnion and chorion, and a small balloon-like sac (chorionic cavity) lying in between the envelopes (Mesh browser). It is also known that a mammalian placenta includes a fetal portion (CHORIONIC VILLI) derived from trophoblasts and a maternal portion (DECIDUA) derived from the uterine endothelium. Thus, the practical questions for practice the invention are which cells could be used for stimulating ES-like cells in the bloodless placenta, how to deplete endogenous cells to provide bedding for the exogenous cells, how to uniformly seed the exogenous cells in such a complicated structure, and how to deliver the nutrients to the seeded cells and the perfused placenta, how to monitor the growth and differentiation of the seeded cells, and how to harvest the propagated cells. The specification is silent with respect to the aforementioned basic questions required for practice the invention. Turning to the state of the art, it is noted that the record has shown there is a size limitation in placenta organ culture, and there is a limited life span for the cells in the post-partum placenta. For example, *Stromberg et al* (Methods in Cell Biol 1980,21:227-52) teach when the cultured placenta (dissected chorionic villi) is submerged in the medium, the necrosis could occur in the central areas of the tissue for specimens even 1-2 mm in size. Even with the improved method introduced by the author, the size could only maximized to 1-1.5 cm (1st paragraph, page 235). Hence, it appears almost impossible to maintain an intact placenta *in vitro* for an extended period of time required for propagation of exogenous cells or for stimulation of ES-like cells without significant necrosis and deterioration of the placenta itself. The specification fails to address these issues, and

thus fails to provide a sufficient guidance to a person of skill intending to practice the claimed invention.

Given the broadest reasonable interpretation in light of the specification, the claimed placenta could be intact with all the endogenous cells and connective tissues of a post-partum placenta. In that case, it is questionable whether exogenous cells would grow and be efficiently propagated in view of the teaching of *Stromberg et al,* who teach only limited success has been achieved in maintaining functional trophoblast cells in monolayer cultures for a short-term primary culture (§ C., page 231). Such limitation has not significantly improved 20 years later as evidenced by *Ma et al* (Tissue Engineering 1999;5:91-102), who teach that the trophoblast cells in the outermost layer of chorionic villi are terminally differentiated and survive no more than about seven days (2nd paragraph, page 92). This seems to be the case for other types of cells in the term placenta such as endothelial cells, *Contractor et al* (Cell Tis Res 1984;237:609-17, e.g. abstract) teach even under nutritional perfusion, oedema and microvillous damage appeared after *three* hours of placenta perfusion. In view of such an environment, it is unlikely that the exogenous cells could be efficiently propagated, and the invention does not appear to be enabled for the intended use in the absence of evidence to the contrary.

Given the broadest reasonable interpretation, the claims also embrace a method using a mammalian placenta depleted of living cells as a scaffold for culturing and harvesting any type of cells from any origin. In view of guidance provided, the specification generally teaches that the endogenous cells could be removed by

irradiation of the perfused placenta with electromagnetic, UV, X-ray, gamma- or beta radiation (paragraph bridging pages 6 and 7). To this end, *Badylak et al* (US 5,866,414) teach using various methods for sterilizing submucosal tissue in culture support (abstract). They teach the technique should not adversely affect the mechanical strength, structure, and more importantly, biotropic properties of the tissue, and they teach that strong gamma radiation may cause loss of strength of the sheets of submucosal tissue (column 3, lines 30-49). Considering the complex form of a cavity with multi-layer membranous tissue of the mammalian placenta, the delicate nature of the term placenta, and many cells are deeply embedded in the multiple layers, neither the art of record nor the specification teaches the proper dosing regimen for killing the cells, and whether they are comparable with the doses of sterilization, and whether the dosage would damage the strength and biotropic property of the placenta tissue, and how to remove the cells since they are not necessarily exposed to the vascular system. Moreover, the specification fails to teach what type of cells are suitable and conditions for growing them in the placenta, whether a human placenta could be used for propagating allogenic and xenogenic cells, the dosing regimen for irradiation so that the cells inside the placenta would lost their viability, yet the strength of the placenta tissue remains, and the specification fails to teach what it takes to remove *all* remain viable endogenous cells since the enzymatic depletion of endogenous cells on record was performed only in fragments of a placenta, and how to collecting the propagated exogenous cells from the placenta after propagation, Therefore, the specification fails to provide an adequate guidance for the skilled artisan intending to practice the invention.

With respect to growing cells with placenta components, it is known that the amniotic membrane comprises the basement membrane and stroma, and could be isolated and preserved (*Tseng*, US 6,326,019, abstract), and that the amniotic membrane, particularly the basement membrane side, could be used as a substrate support for cell culture, particularly for epithelial cells, and for neurons of the peripheral and central nervous system. It is also known that the supporting power of the placenta material is not dependent on living cells but mediated by the amniotic matrix (*Tseng*, US 6,326,019, column 4, lines 13-37). In view of the teaching in the prior art, it appears that the components of basement membrane of amnion is the key to culture support, whereas the perfused placenta further comprises chorion and chorionic cavity. It is unknown and the specification fails to teach whether and what type of cells would grow in these areas. *Madri et al* (J Cell Biol 1983;97:153-165) teach that when exogenous cells were grown on different side of washed, acellular amniotic membranes, their phenotypes were markedly different (e.g. abstract). Hence, with several different types of layers, membranes, and cavities in the placenta, it would be difficult to propagate cells homogenously even if necrosis is not a concern. *Kleinman et al* (US 4,829,000) teach that the polymerized basement membrane components of the placenta could be used for promoting the growth of a variety of cells (column 4, lines 4-15). However, it is not known in the art the efficiency of growing exogenous cells in chorion and chorionic cavity, the types and mode of growth of the cells, and how to collect the cells from the various layers and spaces of an intact placenta since the cells may attached to layers of the membranes, how to isolate and efficiently collect them. With regard to collecting the

propagated cells, the specification is silent about how to get the cells out of the complex bioreactor, or how to separate the debris with the propagated cells if complete breakdown of the placenta is needed. The specification is silent with regard to the aforementioned aspects, and thus fails to provide an enabling disclosure to support what is now claimed.

Claims are drawn to growing exogenous cells regardless of cell type and origin in the term placenta including growing any allogenic, inter-species, and xenogenic animal cells in a human term placenta. *Kleinman et al* disclose a matrixgel derived essentially from the extract of human placenta and teach that the matrigel could reduce the possibility of immune interaction when it is used in humans (column 4, lines 16-21). Apparently, the mammalian placenta does not appear to have immune privilege. Further, *Oppenheim et al* (Theriogenology 2001;55:1567-81) teach that the immune reaction of the placenta causes pregnancy failure in a sheep-goat interspecies hybrid pregnancy (e.g. abstract). In view of such, it is unknown whether allogenic and xenogenic cells are compatible with human placenta substances, and would sufficiently grow in the mammalian placenta, and whether any animal cells would grow in a human term placenta.

Claims 66 and 67 identifies stem cells, particularly primitive stem cells (OCT-4+ and ABC-p+) as the exogenous cells to be propagated in the cell-free placenta. It is well known in the art that the propagation of stem cells requires particular growth factors and culture condition (*Emerson*, Blood 1996;87:3082-8). Although the placenta has provided a proper environment for stem cells during the pregnancy, it is unknown and

the specification fails to teach whether the placenta still can support the propagation of stem cells once it is detached from the uterus and has been made cell free. The specification fails to teach whether and why it is advantages to culture the stem cells in the perfused placenta compared to the culture dish routinely used by the skilled in the art. Accordingly, the specification fails to provide an enabling disclosure to support the intended use of the claimed placenta.

The claimed placenta requires a bloodless condition, however, *Contractor et al* teach that the cells would become severely swelling and vacuolation of the trophoblast after only one hour blood-free perfusion. Accordingly, in the absence of the controdictary evidence found in the reference, the claimed invention does not appear to be enabled to be used for propagating exogenous cells.

With respect to the second utility of the claimed placenta: engrafting a cell not derived from the placenta into the placenta to stimulate the placenta to produce embryonic-like stem cells. Although it is well known in the art that the multipotent hematopoietic stem cells could be obtained from cord blood and placenta of new bourns, the record is silent concerning obtaining stem cells from perfused and bloodless placenta, or stimulating the placenta to produce stem cells. Thus, it is incumbent upon the applicants to provide such evidence in convincing details with respect to the type of cells used for stimulation, the conditions for stimulation, and the types of ES-like cells that could be produced by a bloodless placenta. However, the only evidence disclosed in the specification is the citation of "WO 00/73421" (IDS EJ), which teaches the isolation, cryopreservation, and therapeutic use of human amniotic epithelial cells.

Indeed, the reference used the term "multipotent" for the amniotic epithelial cells. However, the support for multipotency of the cells is that amniotic membrane has been widely used in clinical practice to promote wound healing of various types of epithelial defects. There is no direct evidence either in the cited reference or in other art of record that the amniotic epithelial cells are multipotent, and the wound healing effects are indeed attributed to the multipotency of the amniotic epithelial cells, not other reasons, such as mechanical mechanisms. The specification fails to teach prophetically or by working example what kind of cells could be used to stimulate the placenta for producing the purposed stem cells, and the specification fails to teach what is the theoretical or practical evidence for such discovery, and thus fails to provide an enabling disclosure for what is now claimed. In view of such, the claimed placenta does not appear to be enabled for the intended use.

Given the broadest reasonable interpretation, the claims encompass a placenta obtained at any stage of the pregnancy, however, as indicated in the title of this application, the claimed invention is drawn to a post-partum mammalian placenta. Accordingly, the claims should recite such to be commensurate with the scope of the disclosure.

In conclusion, based on the state of the art and the disclosure of the specification, in view of the quantity of experimentation necessary to determine the parameters for achieving efficient cell propagation in a perfused bloodless term mammalian placenta, in particular for maintaining a large and structural complex placenta for an extended time period, for propagating *any* type of cells and cells from

any origin, the lack of direction or guidance provided by the specification as well as the absence of working examples with regard to *conditions to maintaining the placenta from necrosis and deterioration, culturing stem cells in the cell-free placenta, removing all remaining viable endogenous cells from the placenta, stimulating new cells in the perfused placenta, and collecting the propagated cells from various layers and cavities*, it would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54 and 60-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 is vague and indefinite because of the claim recitation "a cell which is neither fetal nor maternal in origin". Since all cells in a mammalian subject is originated from a fetus in the uterus of a mother, it is unclear what type of cells the instant claim encompasses or excludes, thus, the metes and bounds of the claim is uncertain.

Claim 60 recites the limitation "the isolated mammalian placenta". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The prior rejection of claim 54 under 35 U.S.C. 102(b) as being anticipated by *Ordi et al* (Am J Surg Pathol 1998;8:1006-11), is withdrawn in view of claim amendment and because *Ordi et al* disclosed a biopsy specimen of a placenta, not an isolated intact placenta.

Claim Rejections - 35 USC § 102/103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 54 and 68 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over *MacLaren et al* (J Comp Pathol 1992).

MacLaren et al teach an interspecies goat placenta comprising sheep cells which are neither maternal nor fetal in origin (e.g. abstract and table 1), wherein the placenta has been rinsed (page 281). The placenta disclosed differs from instant claimed in that it does not undergo a perfusion process. However, it is noted that the rinse would wash out at least most of the blood cells, and the perfusion process does not change the

structure of the placenta, only rinse away cord blood remained in the placenta after birth, accordingly, the placenta as claimed appear to be the same in structure and function compared to the placenta disclosed by *MacLaren et al*. Accordingly, instant claims are anticipated or in the alternative obvious over *MacLaren et al*.

Claims 54, 60-65, 68 are rejected under 35 U.S.C. 103(a) as obvious over *MacLaren et al* (J Comp Pathol 1992), in view of *Sanders et al* (US 3,862,002), and *Stromberg et al* (Methods in Cell Biol 1980;21B:227-52), and as evidenced by *Larsson et al* (Angiogenesis 2002;5:107-10).

The teaching of *MacLaren et al* is discussed in detail *supra*. *MacLaren et al* do not teach perfusing the placenta. However, before the instant effective filing date, *Stromberg et al* teach that the human placenta represents a gift from nature for biological investigation in wide variety of subjects (I. Introduction), and the perfusion is on top of the list in study approaches (II. Methods, page 229). *Sanders* teaches that placenta secrets a large number of physiologically active materials which are valuable for research and treatment purpose (column 1, lines 44-63), and provides a method for obtaining such physiologically active placental substances, wherein the method comprises perfusing a human placenta which has been recovered after birth, exsanguinated (isolated) with a sterile medium containing anticoagulant and disinfectant such as broad spectrum antibiotic (column 2, lines 45-62), wherein the perfusion is performed preferably within 6 hrs of delivery (column 3, lines 1-3). *Sanders* teaches exsanguinating and perfusing the placenta in a culture flask apparatus (figures 1-3)

under sterile conditions (column 4, lines 56-67). The perfusion solution taught by *Sanders* contains growth factors because first, the perfusion solution contains human blood plasma (column 5, lines 7-8), which comprising growth factors as evidenced by *Larsson et al*; and second, the placenta would secrete growth factors such as chorionic gonadotropin (column 7, lines 9-61) to the perfusion solution. *Sanders* also teaches that the incubation and perfusion period could last for days since there is a 3-5 day lag for reestablishing the metabolic activity and proliferation of placenta cells after preparation trauma. Thus, *Stromberg* and *Sanders* supplemented the teaching of *MacLaren et al* by establishing the motivation and detailed means for placenta perfusion.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the methods taught by as taught by *Sander et al* and *Stromberg et al* in investigating or obtaining substances from the chimeric placenta as taught by *MacLanren et al* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to do so because the chimeric placenta is apparently the subject of intense studies and it is within the levels of the skill to select a well-known method for such study and arrive at a perfused bloodless placenta. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Q. Janice Li
Primary Examiner
Art Unit 1632

QJL
October 15, 2004